

Notice of Allowability	Application No.	Applicant(s)	
	10/578,734	LIDGREN ET AL.	
	Examiner	Art Unit	
	JAN CHRISTOPHER MERENE	3733	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 3/26/2010.
2. ☒ The allowed claim(s) is/are 1,3,5-13,15-20 and 22-61.
3. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☒ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).
 - * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|---|--|
| <ol style="list-style-type: none"> 1. <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) 3. <input checked="" type="checkbox"/> Information Disclosure Statements (PTO/SB/08),
Paper No./Mail Date <u>See Continuation Sheet</u> 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit of Biological Material | <ol style="list-style-type: none"> 5. <input type="checkbox"/> Notice of Informal Patent Application 6. <input checked="" type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date <u>7/19/2010</u> . 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance 9. <input type="checkbox"/> Other _____. |
|---|--|

/Jan Christopher Merene/
Examiner, Art Unit 3733

/TODD E. MANAHAN/
Supervisory Patent Examiner, Art Unit 3734

Continuation of Attachment(s) 3. Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date: 3/26/2010, 7/20/2009, 7/14/2010.

DETAILED ACTION

Election/Restrictions

1. Claims 1, 61 are directed to an allowable product. Pursuant to the procedures set forth in MPEP § 821.04(B), claims 53, 58, directed to the process of making or using an allowable product, previously withdrawn from consideration as a result of a restriction requirement, claims 53, 58 hereby rejoined and fully examined for patentability under 37 CFR 1.104.

Because all claims previously withdrawn from consideration under 37 CFR 1.142 have been rejoined, **the restriction requirement as set forth in the Office action mailed on June 19, 2009 is hereby withdrawn.** In view of the withdrawal of the restriction requirement as to the rejoined inventions, applicant(s) are advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, a claim that is allowable in the present application, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Once the restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. See *In re Ziegler*, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

EXAMINER'S AMENDMENT

2. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided

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by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Jessica Winchester on July 15, 2010.

The application has been amended as follows:

Claim 1. A system for providing spongy bone with bone substitute and/or bone reinforcing material, including:

at least one perforating device (4) configured to make at least one hole (5) in the spongy bone (1),

at least one flushing or rinsing device (6) configured to flush or rinse the hole (5) with a rinsing agent (7),

at least one supply device (8) configured to supply the bone substitute and/or bone reinforcing material (3) to the hole (5) in the spongy bone (1), and

at least one vacuum source (9) configured to generate a vacuum in the hole (5) in the spongy bone (1), suck the rinsing agent (7) into the hole (5) in the spongy bone (1), and to suck rinsing agent (7) and tissue material out of said hole (5), wherein

said vacuum source (9) is further configured to suck the bone substitute and/or bone reinforcing material (3) into the hole (5) in the spongy bone (1) from the supply device, and wherein

said vacuum source (9) is configured to generate a vacuum of between -0.5 bar and -0.92 bar in the hole (5) of the spongy bone (1).

Cancel **Claim 14**.

Claim 15. The system according to claim 1, wherein the vacuum source (9) is configured to generate a vacuum of between ± 0.7 and ± 0.8 bar in the hole (5) of the spongy bone (1).

Claim 44. The system according to claim 1, further including a bone substitute and/or bone reinforcing material, wherein the bone substitute and/or bone reinforcing material (3) is at least one of a mineral material, a substantially mineral material, a ceramic material, and a substantially ceramic material.

Claim 51. The system according to claim 1, further including a bone substitute and/or bone reinforcing material, wherein the bone substitute and/or bone reinforcing material (3) is a bone cement including a polymer and a monomer, wherein the polymer and monomer harden to bone cement after mixing with each other and after said sucking and/or insertion or feeding thereof into the spongy bone (1).

Claim 53. A method for providing spongy bone with bone substitute and/or bone reinforcing material, wherein:

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at least one hole (5) is made in the spongy bone (1) by at least one perforating device,

the at least one hole (5) is flushed or rinsed with rinsing agent (7) by at least one flushing or rinsing device (6),

the at least one hole (5) is supplied with bone substitute and/or bone reinforcing material by at least one supply device (8), and

a vacuum is generated in the hole (5) for sucking and/or facilitating insertion or feeding of the bone substitute and/or bone reinforcing material (3) into the hole (5) by at least one vacuum source (9), such that the bone substitute and/or bone reinforcing material (3) is sucked into the hole (5) in the spongy bone (1), the vacuum generated is between -0.5 bar and -0.92 bar.

Claim 56. A method for providing spongy bone with bone substitute and/or bone reinforcing material (3) comprising, which is applied or provided in at least one hole (5) in the spongy bone (1) in which a vacuum is generated, wherein applying bone substitute material and/or bone reinforcing material (3) from at least one supply device (8) in at least one hole (5) in spongy bone (1) by generating a pulsating vacuum in the hole (5) by at least one vacuum source (9) such that the bone substitute and/or bone reinforcing material (3) is brought to pulsate during its application in the spongy bone (1), the vacuum generated is between -0.5 bar and -0.92 bar.

Claim 58. A method for providing spongy bone with bone substitute and/or bone reinforcing material (3) comprising:

rinsing at least one hole (5) in spongy bone (1) with rinsing agent by at least one flushing or rinsing device, wherein the rinsing agent (7) is sucked pulsatingly through the hole (5) in the spongy bone (1) by generating a pulsating vacuum by at least one vacuum source (9) in said hole (5), such that the rinsing agent (7) is sucked into the hole (5) in the spongy bone (1), where the vacuum generated in the hole (5) is of between -0.5 bar and -0.92 bar,

applying bone substitute and/or bone reinforcing material (3) from at least one supply device (8) in~~which is applied or provided in a least one~~ the hole (5) in the spongy bone (1) ~~in which~~ by generating a vacuum by the at least one vacuum source (9), is generated and wherein the hole (5) is flushed or rinsed with rinsing agent (7) before application therein of the bone substitute and/or bone reinforcing material (3), wherein the rinsing agent (7) is sucked pulsatingly through the hole (5) in the spongy bone (1) by generating a pulsating vacuum in said hole (5).

Claim 61. A system for providing spongy bone with bone substitute and/or bone reinforcing material, including:

at least one supply device (8) configured to permit the supply of bone substitute and/or bone reinforcing material (3) to a hole (5) in a spongy bone (1); and

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at least one vacuum source (9) configured to generate a vacuum in the hole (5) in the spongy bone (1), and suck the bone substitute and/or bone reinforcing material (3) from the at least one supply device (8) into the hole (5) in the spongy bone (1);

wherein the vacuum source (9) is configured to generate a vacuum of between about -0.5 bar and about -0.92 bar in the hole (5) of the spongy bone (1).

3. The following is an examiner's statement of reasons for allowance: Claims 1, 53, 56, 58, 61 in the instant application have not been rejected using prior art because no references, or reasonable combination thereof, could be found which disclose, or suggest, a system (and a method of using the system) of supplying bone substitute and/or reinforcing material into spongy hole by sucking the material into the hole by a vacuum source, the vacuum source generating a vacuum -0.5 bar and -0.92 bar, the vacuum source also being used to also suck rinsing material into the hole in spongy bone. Riley 6,248,110 discloses a similar system of feeding bone material into bone but fails to disclose a vacuum source operating at between -0.5 to -0.92 bar. Bonutti US 5,269,785 discloses a device with rinsing agent with a vacuum/aspiration source but fails to disclose a generating a vacuum of between -0.5 bar and -0.92 bar. Lidren US 5,238,262 discloses the use of a vacuum to make bone material but fails to disclose the use of a vacuum source for feeding the bone material. Draenert 5,047,030 discloses using a vacuum source to deliver bone cement but does not disclose using negative pressure to suck the cement into the bone in the -0.5 bar to -0.92 bar range. Most of the prior art for applying bone material use syringe type devices with a piston or a

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pressurized means to extrude the bone material into bone but none use negative pressure to suck the bone material from a supply device into the bone.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Conclusion

The prior art made of record and relied upon is considered pertinent to the applicant's disclosure. See PTO-892 for art cited of interest.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JAN CHRISTOPHER MERENE whose telephone number is (571)270-5032. The examiner can normally be reached on 8 am - 6pm Mon-Thurs, alt Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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